IN THE UNITED STATES BANKRUPTCY COURT

FOR THE DISTRICT OF DELAWARE

In re:	)	Chapter 11
	)	
W. R. GRACE & CO., et al.,	)	Case No. 01-01139 (JKF)
	)	(Jointly Administered)
	)	
Debtors.	)	

BRIEF OF W.R. GRACE & CO. IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Rules and Regulations

Other Authorities

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I. INTRODUCTION

In her case management orders, Judge Judith Fitzgerald has directed that these proceedings are to focus solely and specifically on the issue of "what science demonstrates with regard to whether Zonolite Attic Insulation ("ZAI") creates an unreasonable risk of harm." As set forth in detail below, ZAI Claimants have not met their burden to proffer valid scientific evidence sufficient to create a genuine issue of material fact on whether ZAI creates an unreasonable risk of harm.

The parties agree that the mere presence of ZAI in an attic does not release asbestos fibers into the air and that non-airborne fibers pose no health risk. ZAI Claimants base their claims on the alleged hazard posed by ZAI when it is disturbed. The evidence proffered by ZAI Claimants as to the level of airborne asbestos resulting from disturbance or removal of ZAI does not constitute valid scientific evidence. Even if accepted, such evidence would upon proper analysis demonstrate levels well below those established as acceptable by government regulators.

No valid scientific evidence has been proffered as to any causal relationship between ZAI and disease. The evidence falls far short of applicable legal standards as to what constitutes an "unreasonable risk of harm," *i.e.*, whether the presence or disturbance of ZAI

doubles the risk of an asbestos-related disease. Accordingly, summary judgment on this threshold issue should be entered in favor of the Debtors, W. R. Grace & Co., *et al.* ("Grace"), and the claims of ZAI Claimants should be dismissed.

II. BACKGROUND

A. The History of Zonolite Attic Insulation and Vermiculite

ZAI was made of an expanded mineral known as vermiculite. Vermiculite, which is not asbestos, is a lightweight micaceous mineral (*e.g.*, mica) mined from the earth. From the 1920s until operations permanently ceased in 1990, various companies (including Grace beginning with its 1963 acquisition of the Zonolite Company) mined vermiculite ore from Zonolite Mountain, located about ten miles outside of Libby, Montana. The crude vermiculite ore mined near Libby contained various other minerals, referred to here as "tremolite".[1] The tremolite was both asbestiform (*i.e.,* fibrous) and non-asbestiform (*i.e.*, prismatic crystals of rock fragments).

After mining the crude vermiculite ore, Grace milled the ore to remove impurities such as tremolite and the resulting vermiculite was referred to as "vermiculite concentrate." The concentrate was graded by ore size in five grades, number 1 being the largest and number 5 being the smallest. Vermiculite concentrate then was shipped for later "expansion" and processing at expanding plants across the country. Expansion was the heating of vermiculite concentrate in a furnace until it expanded in size like popcorn. Expanded vermiculite from

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1 The term "tremolite" is used herein as a short-hand reference not only to the mineral tremolite, but to various related minerals associated with Libby vermiculite, including actinolite, winchite and richterite. Agency for Toxic Substances and Disease Registry, Year 2000 Medical Testing of Individuals Potentially Exposed to Asbestiform Minerals Associated with Vermiculite in Libby, Montana: A Report to the Community (August 23, 2001) ("ATSDR Medical Testing"), Appendix, Exh. A at 2.

Grades 1 and 2 (and on rare occasions Grade 3) was used in ZAI. ZAI was sold to homeowners as additional attic insulation to be spread in unfinished attics of existing homes. Grace never added commercial asbestos to the product and the percentage of fibrous tremolite in ZAI generally was less than 1%.

The trace amount of asbestiform tremolite in ZAI has been known to the Government and, more particularly, the United States Consumer Products Safety Commission ("CPSC"), for many years. In the early 1980s, when the CPSC had banned the sale of a number of asbestos-containing products, it began investigating ZAI. Grace provided the CPSC with results of air sampling conducted during installation of ZAI. The CPSC elected not to ban ZAI or otherwise regulate it. In about the same time period, the Environmental Protection Agency ("EPA") conducted a similar investigation and exposure assessment of vermiculite attic insulation and also decided not to regulate it.

In 1984, Grace ceased the production of ZAI and, in 1990, the Libby mine was closed.

B. Pre-Bankruptcy Litigation of ZAI Claims

At the time Grace filed for bankruptcy, a number of putative class actions in various federal and state courts had been filed against Grace on behalf of homeowners whose properties contained ZAI. The cases pending in federal court were transferred through the Multi-District Litigation process to Judge Patti B. Saris of the United States District Court for the District of Massachusetts. The cases were generally in their preliminary stages, with discovery ongoing.

With the exception of *Barbanti v. W.R. Grace & Co.,* No. 00-2-01756-6 (Wash. Super. Ct., Dec. 20, 2000) ("*Barbanti*"), no decisions have been reached on the merits of the homeowners' contentions. In *Barbanti,* Judge Kathleen O'Connor held a three-day hearing on a

motion for preliminary injunction brought on behalf of Washington state homeowners by lead counsel for ZAI Claimants in these proceedings. At the conclusion of the hearing, Judge O'Connor denied plaintiffs' motion for preliminary injunction, rejecting the plaintiffs' assertions that an emergency health hazard existed. *Barbanti*, Appendix, Exh. B.

III. PROCEDURAL HISTORY OF THE SCIENCE TRIAL

Upon filing bankruptcy, Grace proposed that the claims of homeowners with ZAI in their properties ("ZAI Claimants") be adjudicated through the filing of individual proofs of claims. Counsel for ZAI Claimants argued that individual proofs of claims were unnecessary and argued for a single proof of claim to be litigated on behalf of a class of ZAI Claimants. Grace then filed individual proofs of claims on behalf of some ten ZAI Claimants. Counsel for ZAI Claimants moved to strike these proofs of claims and the Court denied their motion. Grace next filed objections to ZAI Claimants' proofs of claims and ZAI Claimants filed a response asserting the purported validity of their claims.

Rather than immediately compelling all ZAI Claimants to file individual proofs of claims (which would have required, among other things, approval of the requisite proof of claim form) or permitting ZAI Claimants' claims to proceed as a class action, Judge Fitzgerald decided to address first the fundamental threshold issue of whether ZAI poses an unreasonable risk of harm to human health.

Accordingly, on October 21, 2002, the Court entered an Order (in what has become known as the "ZAI Science Trial") providing "that the scope of discovery will be limited to what science demonstrates with regard to whether ZAI creates an unreasonable risk of harm." The October 21 Order further set a schedule for the ZAI Science Trial which was enlarged by Order dated November 25, 2002.

The November 25 Order set forth deadlines for the completion of fact discovery, service of expert reports and completion of expert depositions, which the parties have met with very minor deviations. The Order further provided that Debtors would file, and ZAI Claimants could file, a Rule 42 consolidation motion together with related *Daubert* summary judgment motions by July 7, 2003, with response briefs due August 8, 2003, and any replies due August 18, 2003. The Order scheduled argument on the motions for September 16 and 17, 2003.

IV. THE EVIDENCE CONCERNING WHETHER ZAI CREATES AN UNREASONBLE RISK OF HARM

The issue presented by Grace's motion is whether ZAI Claimants have proffered admissible scientific evidence sufficient to create a genuine issue of material fact that ZAI presents an unreasonable risk of harm to homeowners or others. Thus, the focus of this Court's consideration of this motion is properly on the scientific evidence proffered by ZAI Claimants. However, the Court should be aware that Grace, through its scientific evidence, can demonstrate that ZAI and disturbances of ZAI by homeowners or others through cleaning, repair, removal or storage activities in an attic do not cause an unreasonable risk of harm.

A. ZAI Claimants' "Scientific Evidence"

In attempting to establish that ZAI creates an unreasonable risk of harm, ZAI Claimants rely primarily upon the following "scientific evidence" of their experts William Ewing, Richard Hatfield, William Longo and Steve Hays:

- Results of samples of dust from attic surfaces (and possibly some air sampling results) that were prepared by the "indirect preparation method."
- Attempts to utilize something called a "K-factor" to convert what is allegedly found in the dust sampling results into an estimate or prediction of what asbestos is in the respirable air.
- Air sampling results from tests performed during certain simulations which results include non-asbestos, non-harmful "cleavage fragments" of rock counted by ZAI Claimants as respirable asbestos fibers.

- Air sampling analysis reported in a way that avoids the scientifically acceptable 8-hour time-weighted averages ("TWA") utilized by regulatory agencies.

- Anecdotal evidence from two factually unique lawsuits which ZAI Claimants allege show a causal connection between ZAI and asbestos-related disease.

- Evidence that disturbing ZAI increases the risk of exposure -- not the risk of disease -- as compared with non-disturbance.

- EPA's Consumer Awareness Program communications concerning vermiculite attic insulation.

- Results from historical experimental testing conducted by Grace that do not distinguish between asbestos and non-asbestos fibers.

Of more significance, perhaps, are three types of scientific evidence which ZAI Claimants do not offer:

- A scientifically acceptable risk assessment analysis establishing that there is an unreasonable risk of harm from exposure to ZAI. *See* page 10 *infra.*

- Epidemiological studies showing that ZAI is associated with asbestos-related disease. *See* pages 32-35 *infra.*

- Any evidence that alleged elevated asbestos exposure levels created during sporadic and infrequent disturbance of ZAI exceed the threshold level of lifetime exposure necessary to present even a theoretical risk of disease. *See* pages 10 - 11 *infra.*

B. Grace's Scientific Evidence

With respect to Grace's scientific evidence, the following facts are not in dispute:

- The mere presence of ZAI in an attic does not release asbestos fibers into the air of either the attic or the living areas of the home. *See, e.g.*, Ewing Dep., Appendix, Exh. C at 58.

- The Occupational Safety and Health Administration ("OSHA") has regulated asbestos in the workplace for over 30 years. Under OSHA regulations, the Permissible Exposure Level ("PEL") for airborne

asbestos fibers is 0.1 fiber per cubic centimeter of air, eight hours a day, five days a week, 52 weeks a year, for 45 years. *See* 29 C.F.R. § 1910.1001 (2003).

- The EPA has regulated asbestos in the environment since the early 1970s and has established conservative criteria for acceptable risks from exposures to various substances. For carcinogens, such as asbestos, the EPA has established that an acceptable risk range is one cancer in 10,000 persons (10^{-4}) to one cancer in 1,000,000 persons (10^{-6}). *See* 40 C.F.R. § 300.430(e)(2)(i)(A)(2) (2003).[2]

Grace has retained three nationally recognized experts to evaluate the risk of exposures to ZAI when it is disturbed in an attic through cleaning, renovation, storage or removal activities, namely:

- Dr. Elizabeth L. Anderson, a former director of the EPA's Risk Assessment Programs, past President of the Society of Risk Analysis and Editor of "Risk Analysis: An International Journal." Elizabeth Anderson Report, Appendix, Exh. E.

- Dr. Morton Corn, former Assistant Secretary of Labor in charge of OSHA, former Professor and Director of the John Hopkins University School of Public Health and author of over 100 articles, book chapters and books on industrial hygiene. Corn Report and Corn Supplemental Report, Appendix, Exh. F.

- Dr. Richard J. Lee, an expert microscopist and physicist, who has performed analysis of asbestos and other materials (including rocks from the moon) for NASA, the EPA, the United States Navy, the United States Army, the State of California and countless other governmental and private organizations. Lee Report, Appendix, Exh. G.

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2 Regulatory risk assessments intentionally encompass the upper range of possible risks. Federal Judicial Center, Reference Manual on Scientific Evidence (2d ed. 2000), Appendix, Exh. D at 413. While the EPA's methodology establishes a very conservative or theoretical acceptable risk range that is considerably higher than the real risk, ZAI Claimants cannot satisfy even this conservative standard. The EPA's conservative risk assessment criteria are based on a linear dose extrapolation which utilizes the conservative assumption that the risk of disease decreases in a linear relationship proportionate to the decrease in dose. This approach, however, likely overstates the risk and the real risk could be considerably lower, even approaching zero. Elizabeth Anderson Report, Appendix, Exh. E at 13.

These experts evaluated one or more of seven different studies that used simulations designed to disturb or remove ZAI in the manner homeowners or others would do so. The studies included personal and area air samples collected and analyzed to measure the airborne asbestos, if any, generated by the disturbances.

The studies evaluated by Grace's experts[3] included:

- a series of simulations performed by plaintiffs' experts in the *Barbanti* case, which included removing ZAI, cutting a hole in the ceiling beneath ZAI, and other activities;
- a series of simulations including cleaning and storage, small scale removal, large scale removal, and renovation, performed at Grace's request by Dr. Peter Lees and Dr. Steve Mlynarek, in a home near Albany, New York;
- a set of simulations done by the EPA involving renovation activities in various homes in Libby, Montana;
- a set of simulations done by Versar, Inc. under a contract from the EPA, involving renovation activities and small and large scale removal;
- demolition of a building in Canada as reported by Pinchin Environmental Group;
- two sets of simulations done for this case by ZAI Claimants' experts -- one in Silver Spring, Maryland and one in the State of Washington.

Dr. Richard Lee is the world's foremost expert in materials characterization and has been analyzing vermiculite and asbestos for over 20 years. Most recently, Dr. Lee has been asked by EPA to devise a standardized protocol for the analysis of vermiculite. Dr. Lee analyzed the air data from the foregoing studies and, when the data are corrected for scientific

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3 The studies are described in detail in the Expert Reports included in Grace's Appendix, Exhs. E, F and G.

errors (*e.g.*, counting non-asbestiform "cleavage fragments" in air samples as respirable asbestos fibers and using the scientifically invalid "indirect preparation method"), Dr. Lee concluded that the air sampling results are all fairly consistent with the air data reported in the study conducted by Drs. Lees and Mlynarek.

On a time-weighted average basis, the Lees-Mlynarek study of cleaning, small scale removal, large scale removal and fan installation activities showed that airborne asbestos concentrations were one-tenth of the OSHA Permissible Exposure Level or lower:[4]

> the asbestos concentrations average 0.002 f/cc, 0.004 f/cc, 0.010 f/cc and 0.010 f/cc, respectively, all of which are significantly below the OSHA permissible exposure limit.

Lee Report, Appendix, Exh. G at 34 (emphasis supplied).

The EPA's simulations in Libby and the studies done by Versar found concentrations consistent with those found in the Lees-Mlynarek studies. *Id.* at 36. After correcting for scientific errors, Dr. Lee found that the results of ZAI Claimants' own simulations were consistent with those found in the Lees-Mlynarek study, which means that these activities also were well below OSHA's 0.1 f/cc PEL. *Id.* at 33-35.[5]

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4 Under OSHA, the PEL for airborne asbestos fibers is 0.1 fiber per cubic centimeter of air ("0.1 f/cc"), calculated and reported as a time-weighted average over eight hours. Under the *Daubert* standard, *see* pages 13 to 14 *infra*, ZAI Claimants' attempt to use air sample analysis to imply anything about risk without calculating an 8-hour time-weighted average for lifetime exposure must be rejected as not scientifically valid. *See* 29 C.F.R. § 1910.1001 (2003); Elizabeth Anderson Report, Appendix, Exh. E at 5-6; Lee Report, Appendix, Exh. G at 40; Corn Supplemental Report, Appendix, Exh. F at 4, 6.

5 Grace recognizes that by law the OSHA regulations apply only in workplace environments, and thus apply to contractors and not to homeowners. Nevertheless, this governmental recognition of an acceptable exposure level for every day of a person's 45-year working life, provides valuable scientific guidance to experts in the field of public health and safety, particularly when compared to a homeowner's infrequent and relatively short duration exposures at insignificant levels.

As Director of the Office of Health and Environmental Assessment at EPA, Dr. Elizabeth Anderson helped create the EPA's risk assessment process, a four-step process that involves: (1) identifying a potential hazard based on animal toxicity or human epidemiological studies; (2) assessing the dose required to cause particular health effects; (3) estimating the exposure from a particular activity; and (4) comparing the exposure and dose-response to estimate the potential risk. This process, or "risk paradigm," is widely accepted and applied in the regulatory and pubic health fields. *See* Elizabeth Anderson Report, Appendix, Exh. E at 8-9.

Dr. Anderson analyzed the foregoing studies and performed a risk assessment according to these standard methods and concluded:

> [T]he low risks that were estimated for residents and contractors are similar to or less than risks that are commonly experienced and accepted by individuals and regulatory agencies, both as the results of environmental causes or other common activities. In addition, the resulting risks are within the acceptable target range of risk, 10^{-4} to 10^{-6}, commonly accepted by EPA and far below risk levels associated with OSHA standards for worker protection.

Id. at 5 (emphasis supplied).

Dr. Morton Corn, former head of OSHA, has been working in the industrial hygiene and public health field for over 30 years. As recognized by Dr. Corn, the potential health risk posed by inhaling airborne asbestos, according to the fundamental tenets of industrial hygiene and public health, is dependent not only on the concentration of asbestos in the inhaled air, but also on the frequency and duration of such exposures over a person's entire lifetime. *See* Corn Report, Appendix, Exh. F at 13, 18-19 and Corn Supplemental Report, Appendix, Exh. F at 4, 6.

Dr. Corn analyzed the foregoing studies from an industrial hygiene perspective and concluded that the studies show that the "dosage of inhaled fibers to the lungs is very low

when compared to the historical lifetime dosages of asbestos inhaled in the past by asbestos workers, or to dosages permitted to be inhaled during a working lifetime with current occupational standards." Corn Report, Appendix, Exh. F at 18. He also concluded that:

> . . . low concentration exposure to airborne asbestos [from ZAI] when it occurs, if it occurs, indicates risks less than those usually regulated by the EPA and not sufficiently high to be regulated by OSHA.

Id. at 19.

Grace also retained Dr. William G. Hughson, a Board-certified pulmonologist and epidemiologist, a Rhodes scholar, and the Director of the Center for Occupational and Environmental Medicine at the University of California at San Diego. Dr. Hughson concluded that whether a person is at an increased risk from exposure to asbestos depends on the level of exposure (dose), the type of asbestos fibers, and the size of the fibers. He also concluded that there are levels of asbestos exposure below which disease has not been shown to occur and that, at the exposure levels that have been quantified for ZAI, there is no practical risk of asbestos disease. Hughson Report, Appendix, Exh. H at 3.

Grace anticipates that ZAI Claimants will argue that the federal government's national consumer awareness program on ZAI reflects a determination by EPA that ZAI creates an unreasonable risk of harm. *See* EPA Headquarters Press Release (May 21, 2003), Appendix, Exh. I; EPA and ATSDR, Current Best Practices for Vermiculite Attic Insulation (May 2003), Appendix, Exh. J. Such an argument, quite simply, is false. Neither the EPA's May 21, 2003 press release, nor the documents issued contemporaneously with it, state that ZAI creates an unreasonable risk of harm to homeowners or others.

In fact, when requested to declare a public health emergency in Libby, Montana due to the alleged hazard presented by ZAI in homes, the EPA refused. As explained by EPA's Office of Pollution Prevention and Toxics ("OPPT") "we do not think a supportable argument

has been made to declare Libby a Public Health Emergency based on the questionable added exposure burdens from ZAI." OPPT Comments on Action Memorandum Amendment Removal Action at the Libby Asbestos Site (Feb. 22, 2002), Appendix, Exh. I at 2.

EPA Administrator Christine Todd Whitman's letters to Senators Baucus and Murray, who had raised questions concerning the EPA's refusal to declare a public health emergency, confirmed that "EPA has not changed its longstanding guidance to homeowners [about ZAI] because we do not have the scientific basis to do so at this time . . . [S]o much about the risks posed from asbestos-containing vermiculite attic insulation remains unknown. . . ." *See* Letters from Christine Todd Whitman, EPA Administrator, to Senators Max Baucus and Patty Murray (April 4, 2003 and April 18, 2003) ("Whitman Letters"), Appendix, Exh. K at 1-2.

In summary, the scientifically and legally acceptable evidence shows that the risks, if any, from occasionally disturbing attic insulation containing trace amounts of asbestos fibers (through storage, cleaning, renovation or removal activities) are well within the risks deemed acceptable and permissible by regulatory agencies and by health and risk professionals.[6] In short, ZAI does not create an unreasonable risk of harm to homeowners or others.

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6 Grace also anticipates that ZAI Claimants will rely upon experimental testing Grace performed in the late 1970s and early 1980s to simulate exposure during the installation of ZAI. In addition to the fact that much of the testing was performed with experimental material, under today's scientific standards the historical testing results are not reliable indicators of airborne asbestos during disturbance of ZAI. The samples were analyzed by Phased Contrast Microscopy (PCM), a method that does not distinguish asbestos from non-asbestos fibers. No attempt was made to perform a differential count to exclude the non-asbestos fibers. As set forth in Dr. Richard Lee's Expert Report, data from studies performed by numerous experts -- including ZAI Claimants' experts own data -- demonstrate that only a small portion (1.5% - 6%) of all fibers counted using the PCM method are actually asbestos fibers. Lee Report, Appendix, Exh. G at 41-42.

V. APPLICABLE LEGAL STANDARDS

A. The *Daubert* Standard Requires The Court To Screen Out Evidence That Is Not Scientifically Valid.

In order to determine what science teaches concerning whether ZAI creates an unreasonable risk of harm, this Court necessarily must examine the science itself. But, the science must be reliable in order to be considered at all.

In *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 589 (1993), the Supreme Court held that federal courts must act as a "gatekeeper" and screen proffered expert testimony to ensure that what is admitted "is not only relevant, but reliable." This gatekeeping obligation extends to all expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999).

Faced with a proffer of expert testimony, the court must make a preliminary assessment of whether the testimony's underlying reasoning or methodology is scientifically valid and properly can be applied to the facts at issue. Many considerations bear on the inquiry, including: whether the theory or technique in question can be (and has been) tested; whether it has been subjected to peer review and publication; its known or potential error rate; the existence and maintenance of standards controlling its operation; and whether it has attracted widespread acceptance within a relevant scientific community. *Id.* at 150.

Courts evaluating the scientific validity of evidence have recognized that "law lags science; it does not lead it." *Rosen v. Ciba-Geigy Corp.*, 78 F.3d 316, 319 (7th Cir.), *cert. denied*, 519 U.S. 819 (1996); Federal Judicial Center, Reference Manual on Scientific Evidence,

Appendix, Exh. D at 24.[7] The courtroom is not the place for scientific guesswork. *Rosen*, 78 F. 3d at 319. As the *Daubert* court recognized:

> [T]here are important differences between the quest for truth in the courtroom and the quest for truth in the laboratory. Scientific conclusions are subject to perpetual revision. Law, on the other hand, must resolve disputes finally and quickly. The scientific project is advanced by broad and wide-ranging consideration of a multitude of hypotheses, for those that are incorrect will eventually be shown to be so, and that in itself is an advance. Conjectures that are probably wrong are of little use, however, in the project of reaching a quick, final, and binding legal judgment -- often of great consequence -- about a particular set of events in the past. We recognize that, in practice, a gatekeeping role for the judge, no matter how flexible, inevitably on occasion will prevent the jury from learning of authentic insights and innovations. That, nevertheless, is the balance that is struck by Rules of Evidence designed not for the exhaustive search for cosmic understanding but for the particularized resolution of legal disputes.

Daubert, 509 U.S. at 596-597.

Under *Daubert*, the court may not admit opinion evidence which is connected to existing data only by the *ipse dixit* ("he himself said it") of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered. *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997). Where the factual basis, data, principles, methods, or their application are called sufficiently into question, the trial judge must determine whether the testimony has a reliable basis in the knowledge and experience of the relevant discipline. *Kumho*, 526 U.S. at 148.

If the proffered evidence is not found to be scientifically accepted and reliable, it cannot be considered.

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7 The Reference Manual on Scientific Evidence was published by the Federal Judicial Center to assist federal judges in recognizing the characteristics and reasoning of "science" as it is relevant in litigation. Appendix, Exh. D at Preface.

B. Summary Judgment Standard

Pursuant to Fed. R. Civ. P. 56(c), summary judgment is appropriate when there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). In particular, summary judgment is warranted where plaintiffs cannot establish an essential element of their claim. *Id.* at 322; *see also Schoonejongen v. Curtiss-Wright Corp.*, 143 F.3d 120, 130 (3d Cir. 1998). The moving party bears the initial responsibility of identifying the absence of a genuine issue of material fact, and this may be done by identifying an absence of admissible evidence to support an essential element in a non-moving party's case. *See Celotex Corp.*, 477 U.S. at 325.

Once the moving party has shown the absence of a genuine issue of material fact as to an essential element of the non-movant's case, the burden shifts to the non-moving party to set forth affirmative evidence and specific facts showing that there is a genuine issue for trial. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249-50 (1986); *see also Aronow Roofing Co. v. Gilbane Bldg. Co.*, 902 F.2d 1127, 1128 (3d Cir. 1990) ("Summary judgment will be granted where the non-moving party fails to 'establish the existence' of an element essential to the case.").

The non-moving party must do more than express doubt as to the truth of the moving party's factual submissions, but must show "concrete evidence from which a reasonable jury could return a verdict in his favor." *Anderson*, 477 U.S. at 256. This evidence must rise above casting "metaphysical doubt" as to a material issue of fact. *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986); *see also Schoch v. First Fidelity Bancorporation*, 912 F.2d 654, 657 (3d Cir. 1990) (neither unsupported claims in pleadings nor conclusory allegations in affidavits establish genuine issues of material fact.).

Alleged scientific evidence that does not meet the test of scientific reliability set forth in *Daubert* cannot be utilized to artificially create an issue of fact for trial, and, thus, be used to defeat a motion for summary judgment. *See Kumho*, 526 U.S. at 148.

VI. ARGUMENT

A. Much Of ZAI Claimants' Evidence Must Be Excluded Under The *Daubert* Standard.

Under *Daubert* and its progeny, this Court must exclude from consideration expert testimony that is not scientifically valid and therefore not reliable. Much of ZAI Claimants' evidence, specifically their sampling evidence, was generated by a methodology that has been held to be scientifically invalid by the United States Bankruptcy Court for the District of Delaware. That court precluded dust sampling results that were offered in support of 600 claims for property damage to buildings from the presence of asbestos-containing floor tile. *In re Armstrong World Industries, Inc., et al.*, 285 B.R. 864 (Bankr. D. Del. 2002). For the reasons relied upon by the *Armstrong* court, this Court should exclude evidence proffered in this case that is based upon such unscientific methodologies.

1. ZAI Claimants' evidence based on dust sampling and indirect preparation must be excluded as not scientifically valid.

There is no dispute between the parties that asbestos fibers "must be in the air to pose a health problem." *See* Environmental Protection Agency, "EPA Response to September 11, Frequently Asked Questions," Appendix, Exh. L at 3; Hays Dep., Appendix, Exh. M at 31 (health risk from asbestos is from inhalation.) It thus comes as no surprise that scientific inquiry and regulatory standards have focused on determining the amount of respirable asbestos fibers in the air.

Pursuant to OSHA regulations, a determination about whether workplace exposure to asbestos is acceptable is made by reference to the PEL, which is expressed in terms of the 8-hour time-weighted average concentration of airborne asbestos fibers of a certain size (longer than 5 microns, with a length at least 3 times the width of the fiber). *See* 29 C.F.R. § 1910.1001 (2003) (OSHA regulation concerning workplace asbestos exposure levels).

For many years, scientists and regulatory agencies such as EPA and OSHA have used the concentration of respirable asbestos in the air that people breathe to assess whether an unacceptable risk is present. In contrast, as conceded by ZAI Claimants' experts, no regulatory standard relies upon measurements of asbestos in settled dust samples to determine hazard. Ewing Dep., Appendix, Exh. C at 163; Hatfield Dep., Appendix, Exh. N at 24. Nonetheless, in this case, ZAI Claimants seek to evaluate whether an unreasonable hazard exists from release of asbestos from ZAI by using a method of analyzing and reporting the concentration of asbestos in dust settled in an attic.

This "settled dust" method was examined and rejected by the Bankruptcy Court for the District of Delaware in *Armstrong*.[8] The "settled dust" method at issue in *Armstrong* was an analytical protocol adopted by the American Society for Testing and Materials ("ASTM") for use in the analysis of surface dust samples utilizing what is referred to as an "indirect preparation method." *See* ASTM D5755, Standard Test Method for Microvacuum Sampling and Indirect

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8 In the case of *In re Lamar County Asbestos Litigation*, slip op. (D.Tex. July 5, 2001), Appendix, Exh. O at 1, the testimony of Richard Hatfield and William Longo was stricken and rejected by the court as being "junk science." Hatfield and Longo's testimony was stricken due in part to their deviation from established methods including improperly mixing direct and indirect methods of dust sample preparation and misusing and misrepresenting TEM analyses. *Id.* The same is true in the present case. In *Ball v. Consolidated Rail Corp.*, 756 N.E.2d 1280, 1289 (Ohio Ct. App. 2001), the Court of Appeals found that an experiment done by Longo did not show the level of asbestos exposure allegedly encountered by plaintiffs in their jobs, and held that his testimony concerning the amounts of asbestos released during the experiment was inadmissible.

Analysis of Dust by Transmission Electron Microscopy for Asbestos Structure Number Concentrations ("ASTM D5755"), Appendix, Exh. P. The method utilized by the claimants in the *Armstrong* case is the same method ZAI Claimants attempt to use in the instant case. *See* Hays Dep., Appendix, Exh. M at 23-24; Hatfield Dep., Appendix, Exh. N at 27-28; Ewing Dep., Appendix, Exh. C at 20-21.

In *Armstrong*, the court found that this method and testimony by some of the same experts proffered here by ZAI Claimants did not meet the standards for admissibility of scientific or technical evidence set forth in *Daubert* and its progeny. *See Armstrong,* 285 B.R. at 886.

The settled dust procedure utilized by ZAI Claimants' experts collects a sample of dust from a surface area using a special microvacuum connected to a filter, allegedly pursuant to the ASTM D5755 protocol. *See* ASTM D5755, Appendix, Exh. P at §§ 8.1-8.8. After collection, the material on the filter is subjected to "indirect preparation": it is washed, put into an acidic solution, shaken, sonicated (bombarded 60,000 times a second by ultrasound), diluted, and then distributed on a new filter for reading under a microscope. This "indirect" sample is then analyzed using transmission electron microscopy (TEM) and the number of asbestos particles are counted. *Id.* at §§ 10.4-15.5.

By contrast, the air monitoring "direct preparation method" -- the method required by OSHA and EPA for air monitoring for regulatory compliance purposes -- examines an air monitoring specimen as it was collected on the initial filter, without washing, shaking, or sonication. Direct preparation of air samples has been found to be the most suitable method for determining the airborne concentration of respirable asbestos. *See Armstrong*, 285 B.R. at 868.

In air monitoring, air is drawn through a hose with a cassette containing an air filter on one end. At the end of the sampling period, the cassette is sealed and shipped to a

testing laboratory. There the filter is removed from the cassette, a sample wedge is cut from it, the sample is examined under a microscope and the number of fibers are counted. *Id.* at 869.

In the *Armstrong* property damage case, Judge Newsome held that the settled dust method and indirect preparation could not be used as a substitute for air monitoring and direct preparation.[9] He held: (1) while the "indirect method" might be a testable hypothesis for measuring asbestos in surface dust, no one has been able to test the hypothesis in a sufficiently controlled fashion, and no one has been able to calculate the exact degree of bias or to identify the exact cause or causes of the bias; (2) the peer review of the method leaves its accuracy in serious doubt; (3) the known or potential rate of error is not quantified; (4) there are standards controlling the technique's operation, but the results flowing from the standards are not calculable; and (5) the indirect method has no relationship to the generally accepted means of measuring the amount of asbestos in the air and the consequent risk of harm. *See id.* at 870-871. Thus, Judge Newsome concluded:

> because there is no statistical correlation between surface dust and airborne dust, and because airborne dust is what poses the risk of harm, the indirect method has no valid scientific connection to the pertinent inquiry.

Id. at 871. *See also In re Lamar County Asbestos Litigation*, Appendix, Exh. O at 6.

In rejecting the settled dust results, the *Armstrong* court stated, "it is generally agreed that the risk of harm from asbestos stems from inhaling fibers, not from how much asbestos is on the surfaces of a room." *Armstrong*, 285 B.R. at 867-868. "Thus, the focus of testing is not on how much asbestos is present in a room or building, but upon how many respirable asbestos structures are in the air during the normal activity." *Id.* at 868.

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9 William Ewing, one of the same experts whose work was rejected in *Armstrong,* is an expert for the ZAI Claimants.

Furthermore, as the *Armstrong* court noted, ASTM D5575 itself concedes that there is no known "single direct relationship between asbestos-containing dust and potential human exposure..." and that the method is not suitable to "evaluate the safety or habitability of buildings with asbestos-containing materials." *Id.* at 869; *see also* ASTM D5575, Appendix, Exh. P at § 5.1.2.

The *Armstrong* court also found that the settled dust method contains bias and variability which preclude it from an admissible scientific method. *Armstrong,* 285 B.R. at 869. The court found that the data from the indirect method "may also suffer from significant variability in the size and number of structures reported by different laboratories preparing and analyzing identical samples." *Id.* at 869. This bias and variability is conceded by ZAI Claimants' own experts. *See* Ewing Dep., Appendix, Exh. C at 163 (With samples from the same spot you can get variances as much as 100%.); Longo Dep., Appendix, Exh. Q at 79-80 (if the same sample were analyzed two times, you could get a range of 2000 fibers per square centimeter to 200,000 fibers per square centimeter).

The *Armstrong* court also found that the number of asbestos structures counted under the indirect method is always higher than through the direct method. *Armstrong*, 285 B.R. at 869. ZAI Claimants' experts concede that this is true. *See* Hatfield Dep., Appendix, Exh. N at 26 (the number of asbestos structures found through the indirect method of preparation is almost always significantly higher than the direct method of preparation.); Ewing Dep., Appendix, Exh. C at 18 ("Generally, the indirect method provides numbers that are higher than the direct method."). [10]

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10 Further, a protocol of the ASTM is required to have a statement of its level of precision and its level of bias. ASTM D5575's precision statement says only that the "precision of the procedure in this test method is being determined." ASTM's bias statement states that because "there is no accepted reference material suitable for determining the bias of the procedure in this test method, bias has not been determined." *See* ASTM D5575,

Continued on following page

Thus, the indirect method injects a clear bias into data generated by the settled dust method. It involves analysis of a second filter after the settled dust sample has been processed from its original filter, which changes the material collected such as by disaggregating a single non-respirable bundle of asbestos into thousands or millions of fibers. *See* EPA, Comparison of Airborne Asbestos Levels Determined by Transmission Electron Microscopy (TEM) Using Direct and Indirect Transfer Techniques (March 1990) ("EPA Comparison"), Appendix, Exh. R at 33; ASTM D5575, Appendix, Exh. P at § 1.4.1.

"Direct preparation" analysis, on the other hand, examines a sample taken directly from the filter on which the specimen was originally collected, without altering the material on the filter. This method has been mandated by both the EPA and the National Institute for Occupational Safety and Health. *See* 40 C.F.R. § 763.90(i) (2003); NIOSH 7400; NIOSH 7402.

Stated differently, the indirect method manipulates the sample taken from the initial filter and multiplies the asbestos structures that one is attempting to count. Washing the filter, adding acid, shaking the sample and sonicating it tend to disaggregate the structures collected on the filter and thus increase the asbestos structure count. *See* EPA Comparison, Appendix, Exh. R at 33. In an EPA study, researchers concluded that the asbestos structure counts from the indirect method ranged from 3.8 to 1700 times higher than structure counts found in samples analyzed by the direct method. *Id.* at 3.

Another factor the court evaluates in determining reliability under *Daubert* is whether the scientific community generally accepts a methodology. *Armstrong* held that settled dust testing was not admissible because its peer review left its accuracy in serious doubt.

Continued from previous page

> Appendix, Exh. P at § 21.2. In short, the indirect TEM method adds an unqualified range of variability to a test that is already fatally flawed at the collection and sampling stage, another reason it is inadmissible. *See Armstrong,* 285 B.R. at 868-869.

Armstrong, 285 B.R. at 870. The method has not been adopted for measuring airborne asbestos by any regulatory agency. *See* Hatfield Dep., Appendix, Exh. N. at 24. Accordingly, ZAI Claimants cannot show that the settled dust method has achieved general acceptance for measuring airborne asbestos.

Finally, the *Armstrong* court determined that the indirect method had a problem with "fit." *Armstrong*, 285 B.R. at 871. Rule 702 requires, in addition to adequate qualifications and methodology, that the proffered expert testimony "assist the trier of fact to understand the evidence or to determine a fact in issue." *U.S. v. Mathis*, 264 F.3d 321, 334 (3d Cir. 2001), *cert. denied*, 535 U.S. 908 (2002). Even if the expert's proffered testimony constitutes scientific knowledge based on a reliable methodology, it will be excluded under the fit requirement if it is not scientific knowledge for purposes of the case. *In re Paoli R.R. Yard PCB Litigation*, 35 F.3d 717 (3d Cir. 1994).

The settled dust method was found not to "fit" in *Armstrong* because it could not establish whether respirable asbestos fibers are or could become airborne -- as they must to pose a threat to human health. The same is true in the present case. The settled dust method tells the user nothing of what is in the air, nor does it tell the user about what is likely to get into the air. *See* Ewing Dep., Appendix, Exh. C at 148-149 (surface dust concentrations are not predictors of past or future exposures.); Hatfield Dep., Appendix, Exh. N at 11 (simply looking at settled dust does not necessarily tell you what is in the air.)

In sum, the use of indirect preparation and dust sampling analysis by ZAI Claimants' experts must be rejected as too unreliable and unscientific to establish that ZAI creates an unreasonable risk.

2. Application of a so-called K-factor does not make dust samples scientifically acceptable to show asbestos in the respirable air.

In an attempt to get from the dust to the air, ZAI Claimants utilize a so-called K-factor. The K-factor is a ratio of asbestos concentrations in air divided by asbestos concentrations in surface dust. *See* Hays Dep., Appendix, Exh. M at 67. Claimants' experts in *Armstrong* conceded that there had never been a K-factor developed for asbestos dust on floor tile. *See Armstrong*, 285 B.R. at 869. The same is true for ZAI -- no peer reviewed K-factor has been developed. Hays Dep., Appendix, Exh. M at 71-72.

ZAI Claimants' experts concede that the K-factor cannot estimate what was in the air at any time in the past, but they claim it is better utilized for attempting to predict what could be in the air in the future due to some disturbance of ZAI or settled dust. *See* Hatfield Dep., Appendix, Exh. N at 29. However, ZAI Claimants' experts readily concede that the K-factor cannot be used to predict the level of airborne asbestos entrained from the dust. *Id.*

As used here by ZAI Claimants, the K-factor has no scientific validity and therefore demonstrates nothing on the issue of whether ZAI creates an unreasonable risk of harm. The K-factor was not accepted in the *Armstrong* case and should not be accepted here. ZAI Claimants cannot use the K-factor to attempt to predict airborne asbestos exposures.

3. ZAI Claimants' air sampling results which count non-dangerous, non-disease producing, non-asbestiform rock fragments as respirable asbestos fibers must be excluded.

As explained by Drs. Lee and Ilgren, asbestos minerals, such as tremolite, have non-asbestos analogs commonly referred to as "cleavage fragments." *See* Lee Report, Appendix, Exh. G at 11; Ilgren Report, Appendix, Exh. S at 4. Cleavage fragments are non-fibrous, non-asbestos minerals:

> When non-asbestiform cleavage minerals such as amphiboles are crushed, fragments are cleaved away from the main crystal mass, a process that produces "cleavage fragments." The massive mineral will tend to fracture along sets of systematic planes within the mineral crystal, and some long thin fragments may result, although the majority of the fragments will be short, non-fibrous particles.

Lee Report, Appendix, Exh. G at 11.

Cleavage fragments are not harmful because generally they are too thick to be respired and are too wide to penetrate deep into the lung. Further, cleavage fragments have numerous surface defects, including surface irregularities and cracks, that make them brittle, weak and more susceptible to acid dissolution, thus causing them to disintegrate completely or break down into smaller particles that are short enough to be cleared from the body. *See* Ilgren Report, Appendix, Exh. S at 5-10. Cleavage fragments are non-asbestiform and "lack the strength, durability, flexibility and acid resistance of asbestos [and] are unable to persist in the body in a manner similar to asbestos." *Id.* at 16. For these reasons, epidemiological studies have demonstrated that cleavage fragments are not associated with asbestos-related disease. *Id.* at 11-15.

ZAI Claimants' experts agree that cleavage fragments are not asbestiform. *See* Ewing Dep., Appendix, Exh. C at 85-86; Hays Dep., Appendix, Exh. M at 24-25. Because

cleavage fragments are not asbestos fibers, they should not be counted as asbestos fibers. Lee Report, Appendix, Exh. G at 13-16.

In fact, after receiving submissions and conducting hearings, OSHA explicitly excluded cleavage fragments from its asbestos regulations. *Id.* In the Preamble to the 1992 Final Rule on Occupational Exposure to Asbestos, Tremolite, Anthophyllite and Actinolite, Intro to 29 C.F.R. Parts 1910 and 1926, OSHA removed cleavage fragments from its asbestos regulations. *See* 29 C.F.R. § 1926.1101 (2003).

Nonetheless, ZAI Claimants' experts inappropriately count the non-asbestos cleavage fragments as asbestos fibers, thereby inflating their asbestos counts. Messrs. Ewing and Hatfield acknowledged that under their methodology cleavage fragments would be counted, testifying that so long as a particle met the counting criteria (*i.e.*, greater than 5 microns in length with an aspect ratio of 3 to 1 or greater), it was counted as asbestos. Ewing Dep., Appendix, Exh. C at 115; Hatfield Dep., Appendix, Exh. N at 65. Although Dr. Longo also recognized that he counted any particle meeting the counting criteria as asbestos, he claimed that all such particles counted were, in fact, asbestos fibers and not cleavage fragments. Longo Dep., Appendix, Exh. Q at 22-26.

However, as set forth in Dr. Richard Lee's expert report, the analysis and characteristics of the particles examined from various simulations -- including ZAI Claimants' own data -- demonstrate that the overwhelming majority of the particles that are released when disturbing ZAI are non-asbestos cleavage fragments that should be excluded from asbestos fiber counts. Lee Report, Appendix, Exh. G at 30-32.

The data demonstrates that ZAI Claimants' estimated air concentrations would be reduced at least "ten-fold" if the non-asbestos cleavage fragments in their samples were excluded. *Id.* at 6. Due to the inclusion of cleavage fragments in ZAI Claimants' air sampling results, said results, like the dust sampling results, are not scientifically reliable.

In any event, the risk assessment performed by Dr. Elizabeth Anderson included an assumption that all particles identified by Dr. Lee as cleavage fragments were actually asbestos fibers. Thus, even including the non-asbestos cleavage fragments among the asbestos counts, Dr. Anderson concluded that the theoretical risk of disease would still be within the conservative range deemed acceptable by federal regulatory agencies. Elizabeth Anderson Report, Appendix, Exh. E at 52.

4. Anecdotal evidence of persons with ZAI exposure who have allegedly contracted asbestos-related disease must be excluded.

The primary scientific tools to ascertain risks from exposure to a substance are epidemiological studies. *See* pages 31-33 *infra*. ZAI Claimants, however, cannot point to a single epidemiological study establishing a relationship between exposure to ZAI and asbestos disease.

Lacking any epidemiology, ZAI Claimants seek to show that ZAI creates an unreasonable risk of disease by offering anecdotal medical evidence or case reports, that is, individual case reports of two persons who have allegedly contracted asbestos-related disease from exposure to ZAI. ZAI Claimants' anecdotal medical evidence, however, fails the *Daubert* standard because: (1) such evidence, by definition, cannot establish medical causation, or "cause-and-effect;" and (2) ZAI Claimants' medical expert, Dr. Henry Anderson, did not have an adequate factual foundation upon which to reach any causation conclusions in those cases.

The Reference Manual on Scientific Evidence explains that anecdotal evidence is not a valid scientific substitute for epidemiological studies in evaluating medical causation issues:

> "Anecdotal evidence" means reports of one kind of event following another. Typically, the reports are obtained haphazardly or selectively, and the logic of "post hoc, ergo propter hoc" does not suffice to demonstrate that the first event causes the second. Consequently, while anecdotal evidence

> can be suggestive, it can also be quite misleading. For instance, some children who live near power lines develop leukemia; but does exposure to electrical and magnetic fields cause this disease? The anecdotal evidence is not compelling because leukemia also occurs among children who have minimal exposure to such fields. It is necessary to compare disease rates among those who are exposed and those who are not. If exposure causes the disease, the rate should be higher among the exposed, lower among the unexposed. Of course, the two groups may differ in crucial ways other than the exposure. For example, children who live near power lines could come from poorer families and be exposed to other environmental hazards. These differences could create the appearance of a cause-and-effect relationship, or they can mask a real relationship. Cause-and-effect relationships often are quite subtle, and carefully designed studies are needed to draw valid conclusions.

Federal Judicial Center, Reference Manual on Scientific Evidence, Appendix, Exh. D at 91-92.

Anecdotal medical reports lack the controls (*i.e.*, the comparison of exposed groups with unexposed groups) of epidemiological studies, and, therefore, fail to eliminate other potential explanations for the disease found. *In re Breast Implant Litigation*, 11 F.Supp. 2d 1217, 1230-31 (D. Colo. 1998). In epidemiological terms, case reports fail to eliminate chance association, confounding factors and bias, and are therefore scientifically invalid as a basis for a medical causation opinion. *Glastetter v. Novartis Pharm.*, 107 F. Supp. 2d 1015, 1030 (E.D. Mo. 2000), *aff'd*, 252 F.3d 986 (8th Cir. 2001).

In addition, many courts have noted that individual case reports reflect "nothing more than a temporal relationship between exposure and a particular occurrence" which is insufficient to prove medical causation. *Glastetter,* 107 F. Supp. at 1030; *Downs v. Perstorp Components, Inc.*, 126 F. Supp. 1090, 1126 (E.D. Tenn. 1999) ("Forming a conclusion on the basis of temporal proximity,... is inconsistent with the scientific method because the expert fails to consider other possible explanations."); *In re Breast Implant Litigation*, 11 F. Supp. 2d at 1224 ("A temporal relationship by itself, provides no evidence of causation.").

Due to the lack of control groups, one can only draw speculative hypotheses, and not proven theories of causation, from individual case report data.

> [T]he generally accepted view in the scientific community is that her methodology [case reports and animal studies] can be used to generate hypotheses about causation, but not causation conclusions. [S]cientifically valid cause and effect determinations depend on controlled clinical trials and epidemiological studies....

In re Breast Implant Litigation, 11 F. Supp. 2d at 1232 (*quoting Haggerty v. Upjohn Co.*, 950 F. Supp. 1160, 1164 (S.D. Fla. 1996)).

The fundamental scientific limitations of anecdotal medical evidence have led federal courts to consistently reject individual case reports as a reliable basis for medical causation opinions. *Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316-17 (11th Cir. 1999) (case studies do not supply scientific knowledge upon which an opinion can be based under *Daubert.)*; *Glastetter v. Novartis Pharm.,* 107 F. Supp.2d at 1028-1031 (two cases of women taking drug who develop injury are not reliable evidence.); *Hollander v. Sandoz Pharm. Corp.*, 95 F. Supp.2d 1230 (W.D. Okla. 2000), *aff'd in pertinent part*, 289 F.3d 1193 (10th Cir. 2002), *cert. denied*, 123 S. Ct. 697 (2002) (case reports have been repeatedly rejected as a scientific basis for a conclusion regarding causation.); *Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp.2d 1153 (D. Mont. 1999) (case reports are compilations of occurrences and have been rejected as reliable scientific evidence.*)*; *In re Breast Implant Litig.,* 11 F. Supp.2d at 1224 (case reports are universally regarded as insufficient.); *Casey v. Ohio Med. Prod.*, 877 F. Supp. 1380, 1385 (N.D. Cal. 1995) (case histories do not rise to the level of scientific reliability, methodology or validation required by *Daubert.)*; *Wade-Greaux v. Whitehall Laboratories, Inc.,* 874 F. Supp. 1441, 1452 (D. V.I. 1994) (case reports do not constitute epidemiologic data or studies.); Reference Manual on Scientific Evidence, Appendix, Exh. D. at 91.

The unreliability of such anecdotal reports is reflected in ZAI Claimants' anecdotal evidence proffered by their medical expert, Dr. Henry Anderson, that Messrs. Edward Harashe and Gerald Liebsch contracted mesothelioma from exposure to ZAI. In both cases, however, Dr. Anderson lacked an adequate foundation to conclude that the disease was caused by exposure to ZAI and not by their other, occupational, exposures to asbestos. *See In re "Agent Orange" Product Liability Litigation*, 611 F. Supp. 1267 (E.D.N.Y. 1985) (excluding expert's causation testimony as lacking adequate foundation because information on plaintiff's toxic exposure and on alternative exposures was "sketchy and unreliable").

With respect to Mr. Harashe, Dr. Anderson admitted that the only basis he has for his opinion is his reading of the appellate court opinion in Mr. Harashe's personal injury lawsuit. Henry Anderson Dep., Appendix, Exh. T at 71 ("All I have is the Court's opinion. I have not reviewed his case other than what is there. I'm taking what's in that as being the facts of the case.").

Beyond that, Dr. Anderson admitted that he did not have information concerning Mr. Harashe's work as a maintenance worker with the St. Louis school district which could have resulted in occupational asbestos exposure. *Id.* at 82-84. Dr. Anderson admitted that he had no information concerning the amount of exposure Mr. Harashe had to ZAI and that such information was necessary to determine if the amount of ZAI exposure was adequate to cause disease. *Id.* at 84-85.

Tellingly, Dr. Anderson admitted that he was not asked to form his own individual opinion regarding Mr. Harashe, but rather is only reflecting the opinions of others. *Id.* at 72. Dr. Anderson conceded that he is not saying that ZAI exposure caused Mr. Harashe's mesothelioma:

> Q. That's what I'm asking you. You came here with the report that says that Mr. Harashe's mesothelioma was caused by exposure to Zonolite Attic Insulation, and your only basis for that opinion is what you read that a

> Court said. You didn't read one medical record. You didn't talk to one physician. You didn't read one medical article about Mr. Harashe's case. Your entire opinion is based on reviewing a Court decision?
>
> A. The summary of the testimony and the Court decision. As I say here, as one of the pieces of evidence I'm saying that unprotected individuals can be exposed and I say can cause mesothelioma. It doesn't say -- it's evidence to support that. I'm not saying in this case I'm concluding that.

Id. at 73-74 (emphasis supplied).

With respect to Mr. Liebsch, Dr. Anderson reviewed certain medical records and deposition transcripts from the personal injury lawsuit brought by Mr. Liebsch's children. Dr. Anderson admitted, however, that he did not review all of the depositions in the case, and that he assumed that Mr. Liebsch had no occupational exposure to asbestos. *Id.* at 86-102. Dr. Anderson also admitted that he did not know that Mr. Liebsch worked in the boiler room of a hospital, that his family members testified that he came home from work covered with white dust, and that he told his wife to wash his clothes separately from the rest of his clothes because of what he was coming into contact with. *Id.* at 99-100.

Likewise, Dr. Anderson admitted he was not aware of Mr. Liebsch's work on cars, including work with brakes that can contain asbestos. *Id.* at 104-107. He also acknowledged that Mr. Liebsch's medical records indicated that he had previous heavy asbestos exposure in his youth. *Id.* at 87-88. He admitted that the depositions were inconsistent regarding Mr. Liebsch's asbestos exposure and that "in general the level of information was fairly sketchy." *Id.* at 117. Finally, as with Mr. Harashe's case, Dr. Anderson admitted that he had no quantification of Mr. Liebsch's exposure to ZAI. *Id.* at 92.

ZAI Claimants' anecdotal medical evidence must be excluded. Such evidence, by definition, cannot establish medical causation, because as a general principle, anecdotal evidence is not reliable, and because of Dr. Anderson's lack of foundation to support his conclusions that Mr. Harashe's and Mr. Liebsch's mesotheliomas were caused by ZAI exposure.

B. ZAI Claimants Have No Epidemiological Evidence That Raises A Genuine Issue Of Material Fact Concerning Whether ZAI Creates An Unreasonable Risk of Harm.

Principles of epidemiology, as applied in numerous lawsuits, require that to establish an unreasonable risk of disease from ZAI, it must be shown that the presence or disturbance of ZAI doubles the risk of asbestos-related disease, that is, that persons exposed to ZAI are at least twice as likely as unexposed persons to contract an asbestos-related disease. It is not enough to show that asbestos can cause disease and that ZAI has asbestos in it.

In fact, ZAI Claimants have no study showing any risk from ZAI, let alone a risk that is twice the disease risk to which the general public is exposed.

The only available medical testing that included a study of ZAI shows no excess risk. That study, which explicitly identified a group of Libby residents whose only known asbestos exposure was the presence of ZAI in their homes and/or the handling of ZAI, was sponsored by the United States Agency for Toxic Substances and Disease Registry ("ATSDR"). The ATSDR's reports found no association between asbestos disease and living in a home with ZAI or having "handled" ZAI. ATSDR, Year 2000 Medical Testing of Individuals Potentially Exposed to Asbestiform Minerals Associated with Vermiculite in Libby, Montana: A Report to the Community, (August 23, 2001) ("ATSDR Medical Testing") Appendix, Exh. A; ATSDR, Preliminary Findings of Libby, Montana, Asbestos Medical Testing [Combined Testing 2000 and 2001], (September, 2002) ("ATSDR Preliminary Findings"), Appendix, Exh. U; Whitman Letters, Appendix, Exh. K, Responses at 2; Elizabeth Anderson Report, Appendix, Exh. E at 50-51.

EPA Administrator Christine Todd Whitman confirmed this finding of a lack of association in response to inquiries into EPA's action at Libby: "The [ATSDR Libby Medical Screening] study did not show that insulation [ZAI] by itself, could be linked with the health impacts found in Libby." Whitman Letters, Appendix, Exh. K, Responses at 2.

1. ZAI Claimants must show through epidemiological studies that the presence or disturbance of ZAI doubles the risk of asbestos-related disease.

Epidemiological studies provide "the primary generally accepted methodology for demonstrating a causal relation between a chemical compound and a set of symptoms or disease." *Siharath v. Sandoz Pharmaceuticals Corp.*, 131 F. Supp.2d 1347, 1356 (N.D. Ga. 2001), *aff'd*, 295 F.3d 1194 (11th Cir. 2002). In the absence of an understanding of the biological and pathological mechanisms by which disease develops, epidemiological evidence is the most valid type of scientific evidence of toxic causation. *In re Breast Implant Litigation*, 11 F. Supp.2d at 1224 (*quoting* Reference Manual on Scientific Evidence); *see also Hollander,* 95 F. Supp.2d at 1235 n.14 (*quoting In re Breast Implant Litigation*).

Where the alleged exposures are of an identifiable group or community, making an epidemiological study possible, such evidence should be submitted to establish causation. *Renaud v. Martin Marietta Corp.*, 749 F. Supp. 1545, 1553-1555 (D. Colo. 1990) (epidemiological evidence should have been submitted to support causation of disease by toxins in water where claim was that community had been exposed to contaminants.); *see also Allen v. Pennsylvania Engineering Corp.*, 102 F.3d 194, 197 (5th Cir. 1996) ("Undoubtedly, the most useful and conclusive type of evidence in a case such as this is epidemiological studies.").

Epidemiologic evidence identifies agents that are associated with an increased risk of disease in groups of individuals, quantifies the amount of excess disease that is associated with an agent, and provides a profile of the type of individual who is likely to contract a disease after being exposed to an agent. Reference Manual on Scientific Evidence, Appendix, Exh. D at 335-345. *See also Siharath*, 131 F. Supp. 2d at 1356; *In re Breast Implant Litigation*, 11 F. Supp. 2d at 1224; *Hall v. Baxter Healthcare Corp.,* 947 F. Supp. 1387, 1454 (D. Or. 1996).

In evaluating such studies, the epidemiologist must analyze the data according to established statistical methods and express the association between an agent and disease in terms

of relative risk. Relative risk is the ratio of incidence of disease in the exposed group to incidence in the unexposed group. The incidence rate expresses the risk that a member of the group will develop the disease within a specified period of time. If the relative risk equals one (1), the risk to the exposed individuals is the same as the risk to unexposed individuals and there is no association between exposure to the agent and disease. Reference Manual on Scientific Evidence, Appendix, Exh. D at 348-349.

Although they have not even done so, it would not be enough for ZAI Claimants to show that there is some increased risk of disease from exposure to ZAI. To meet their "more likely than not" burden, ZAI Claimants have to show that those exposed to ZAI have a relative risk of at least two (2), which means that those exposed are twice as likely to get a disease than those not exposed. *Allison,* 184 F.3d at 1315 n.16; *Daubert v. Merrell Dow Pharm.*, 43 F.3d 1311, 1320-21 (9th Cir. 1995); *Siharath,* 131 F. Supp.2d at 1358; *In re Breast Implant Litig.*, 11 F. Supp.2d at 1227-1228; *Sanderson v. Int'l Flavors and Fragrances, Inc.*, 950 F. Supp. 981, 998 (D. Cal. 1996); *Hall,* 947 F. Supp. at 1403; *Marder v. G.D. Searle & Co.*, 630 F. Supp. 1087, 1092 (D. Md. 1986); Reference Manual on Scientific Evidence, Appendix, Exh. D at 384. *See also* David L. Faigman, et al., 4 Modern Scientific Evidence (2d ed. 2002), Appendix, Exh. V at § 35-1.4.1 at 155-56.

Under *Daubert*, a party attempting to establish causation between a toxic agent and disease may rely only upon epidemiologic studies reflecting a relative risk of two or greater. In *Daubert*, the Supreme Court remanded the case back to the district court for findings consistent with its opinion. Upon remand, the district court granted defendant's motion for summary judgment, finding that plaintiffs' expert testimony that Bendectin had caused plaintiffs' birth defects was invalid under the Supreme Court's standard. *Daubert*, 727 F. Supp. 570, 575 (9th Cir. Cal. 1991).

On appeal, the Ninth Circuit court affirmed and discussed the application of the Supreme Court's standard to epidemiologic evidence of causation:

> None of plaintiffs' epidemiological experts claims that ingestion of Bendectin during pregnancy more than doubles the risk of birth defects. To evaluate the relationship between Bendectin and limb reduction defects, an epidemiologist would take a sample of the population and compare the frequency of birth defects in children whose mothers took Bendectin with the frequency of defects in children whose mothers did not. *See DeLuca,* 911 F. 2d 941 at 946. The ratio derived from this comparison would be an estimate of the "relative risk" associated with Bendectin. *See generally* Joseph L. Fleiss, *Statistical Methods for Rates and Proportions* (2d ed. 1981). For an epidemiological study to show causation under a preponderance standard, "the relative risk of limb reduction defects arising from the epidemiological data . . . will, at a minimum, have to exceed '2'." *DeLuca,* 911 F.2d at 958. That is, the study must show that children whose mothers took Bendectin are more than twice as likely to develop limb reduction birth defects as children whose mothers did not.
>
> * * * *
>
> A relative risk of less than two . . . actually tends to *dis*prove legal causation, as it shows that Bendectin does not double the likelihood of birth defects.

Daubert, 43 F.3d 1311, 1320-1321 (9th Cir. 1995) (footnotes omitted).

Similarly, the court in *Siharath*, evaluated plaintiff's causation evidence under the *Daubert* standard and held that "the threshold for concluding that an agent was more likely than not the cause of a disease is a relative risk greater than 2.0." 131 F. Supp. at 1356. The court rejected plaintiff's expert causation testimony relating to ingestion of the prescription drug Parlodel and stroke because the epidemiologic studies were inadequate. *Id.* at 1359.

In *In re Breast Implant Litigation*, the court recognized that under the "more likely than not" standard, causation must be proven within reasonable probability. 11 F. Supp.2d at 1226. The court held that this meant that plaintiffs must present expert testimony demonstrating that exposure to breast implants more than doubled the risk of their alleged injuries. *Id.* The court examined the proffered epidemiologic evidence and found that none

concluded that breast implants doubled the risk of any known disease. *Id.* at 1227-1228. *See also Allison*, 184 F.3d at 1315, and *Hall*, 947 F. Supp. at 1403 (in both of these breast implant cases, the courts determined that the threshold for concluding that an agent was more likely the cause of a disease than not is a relative risk greater than 2.0.); *Marder*, 630 F. Supp. at 1092 (in evaluating a claim that seventeen plaintiffs' IUDs caused them injury, court recognized that a two-fold increased risk is an important showing for plaintiffs to make because it is the equivalent of the required legal burden of proof--a showing of causation by the preponderance of the evidence or, in other words, a probability of greater than 50%.).

In the instant case, ZAI Claimants proffer no evidence of relative risk, let alone evidence of a doubled risk. In fact, as stated above, the ATSDR's medical testing at Libby did not find any association between asbestos disease and living with ZAI or handling ZAI. Whitman Letters, Appendix, Exh. K, Responses at 2 ("The [ATSDR Libby Medical Screening] study did not show that insulation [ZAI] by itself, could be linked with the health impacts found in Libby."); ATSDR Medical Testing, Appendix, Exh. A; Henry Anderson Dep., Appendix, Exh. T; ATSDR Preliminary Findings, Appendix, Exh. U; Elizabeth Anderson Report, Appendix, Exh. E at 50-51.

2. ZAI Claimants' "no safe threshold" contention is not credible scientific evidence.

Because they have no epidemiologic evidence to support an increased risk of disease from ZAI, Claimants argue there is a risk of disease from any exposure to any amount of asbestos and, because there are asbestos fibers in ZAI, there is "some exposure," and therefore an unreasonable risk. Such reasoning is known as the "no safe level" or linear "no threshold" model.[11] This linear "no threshold" model is used in the regulatory context where the goal is to

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11 This model flies in the face of the toxicological law of dose-response, that is, that "the dose makes the poison", which refers to the general tendency for greater doses of a toxin

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set conservative and precautionary "action levels," not to impose liability. ZAI Claimants' "no threshold" argument, however, does not meet the *Daubert* standard and has been consistently rejected by the courts.

In *Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp.2d 942 (E.D. Ark. 1998), *aff'd,* 191 F.3d 858 (8th Cir. 1999), the court rejected plaintiff's "no threshold" theory. In that case, plaintiff claimed that his laryngeal cancer was caused by his exposure to a toxin in aerosolized milk at a cheese plant where he worked. *Id.* at 944. The court rejected plaintiff's expert causation testimony because the expert presented no scientific knowledge or information as to the level of the toxin that would subject a person who breathes it to an appreciable risk of laryngeal cancer. *Id.* at 946. In reaching its conclusion, the *Nat'l Bank* court said that establishing that the risk of causation "is not zero" falls woefully short of the degree of proof required by *Daubert* and its progeny. *Id.* at 961.

Sutera v. Perrier Group of America, Inc., 986 F. Supp. 655 (D. Mass. 1997) likewise rejected a plaintiff's "no threshold" argument. In that case, plaintiff's expert opined that plaintiff's leukemia was caused by benzene in his bottled drinking water because there is no established threshold level of risk for highly toxic leukemogenic agents such as benzene. In so concluding, plaintiff's expert relied upon the EPA's goal of 0 ppb for benzene in drinking water. *Id.* at 657.

In *Sutera*, plaintiff attempted to buttress his "no threshold" argument by pointing to the fact that various government regulatory agencies have adopted the so-called linear, "no threshold" approach to regulating cancer-causing agents, or carcinogens. The *Sutera* court held,

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> to cause greater severity of responses in individuals, as well as greater frequency of response in populations. Reference Manual on Scientific Evidence, Appendix, Exh. D at 475.

however, that a regulatory standard, rather than being a measure of causation, is a public-health exposure level that an agency determines pursuant to statutory standards set by Congress. *Id.* at 665.

The court found that "the agencies' threshold of proof is reasonably lower than that in tort law, which traditionally makes more particularized inquiries into cause and effect and requires a plaintiff to prove that it is more likely than not that another individual has caused him or her harm." *Id.* at 664-665 (*quoting Wright v. Willamette Indus. Inc.*, 91 F.3d 1105 (8th Cir. 1996)); *see also Allen*, 102 F.3d at 198; *National Bank*, 22 F. Supp. 2d at 961.

Moreover, even the government agencies that employ the conservative linear "no threshold" model for regulatory purposes acknowledge that there are levels of exposure to toxic agents that do not present any real risk of harm. For example, the EPA, notwithstanding its very conservative approach to carcinogens, has established that an acceptable risk range for such substances is a range between one cancer in 10,000 persons (10^{-4}) and one cancer in 1,000,000 persons (10^{-6}). *See* 40 C.F.R. § 300.430(e)(2)(i)(A)(2) (2003). The very recognition of an acceptable risk range is, by definition, a rejection of the "no safe level" argument.

ZAI Claimants' medical expert, Dr. Henry Anderson, has also conceded that there are levels of exposure to the asbestos in ZAI that are not medically significant:

Q: Are there levels at which there wouldn't be a risk [from exposure to the asbestiform tremolite in ZAI]?

A: I would say there certainly could be levels where there wouldn't be a significant level of risk.

Q: So that a person could be exposed to insignificant levels of airborne tremolite fibers?

A: Yes. Sure. All exposure would carry some risk, but, from a public health perspective, it would not be considered to be of significance.

Q: Can you quantify the difference between significant and insignificant in terms of level of exposure?

A: I would say in general a good cut point is if you calculate a risk, a cancer risk, of one in a million is generally viewed as diminimus [sic].

Q: So a risk of one in a million or less is a diminimus [sic] cancer risk?

A: Right. From a regulatory standpoint. Then from practical individual purposes less than that is certainly not a priority risk.

Henry Anderson Dep., Appendix, Exh. T at 63-64.

The Eighth Circuit Court in *Wright v. Willamette Industries, Inc.*, 91 F. 3d 1105 (8th Cir. 1996), decided a claim involving exposure to formaldehyde emissions, holding that it is not enough for a plaintiff to show that a certain chemical agent sometimes causes the kind of harm that he or she is complaining of. At a minimum, there must be evidence that plaintiff was exposed to levels of that agent that are known to cause the kind of harm that the plaintiff claims to have. *Id.* at 1106; *see also Mancuso v. Consol. Edison Co. of New York,* 56 F. Supp.2d 391 (S.D.N.Y. 1999) (there was no reliable scientific basis to believe that any PCB contamination of the marina posed any threat of cancer to the plaintiffs.).

In sum, in the absence of admissible, reliable, scientific evidence that the presence or disturbance of ZAI in a home doubles the risk of contracting an asbestos disease, summary judgment must be entered for Grace.

VII. CONCLUSION

To satisfy their burden to proffer valid scientific evidence sufficient to create a genuine issue of material fact on whether ZAI creates an unreasonable risk of harm, ZAI Claimants must demonstrate that the presence or disturbance of ZAI doubles the risk of contracting an asbestos-related disease. ZAI Claimants' "evidence" falls far short of this standard.

ZAI Claimants agree that the mere presence of ZAI in an attic does not release asbestos fibers into the air and that non-airborne fibers pose no health risk. Rather, ZAI

Claimants base their claim on an alleged hazard posed by ZAI when it is disturbed. However, they fail to proffer any scientifically valid evidence that alleged elevated asbestos exposure levels created during sporadic and infrequent disturbance of ZAI come anywhere near exceeding the level of lifetime exposure necessary to present even a theoretical increased risk of disease.

In fact, much of the "evidence" ZAI Claimants proffer -- evidence based on "indirect preparation" and dust sampling, evidence based on the so-called K-factor, evidence based on air sample analyses that count as asbestos fibers non-dangerous, non-asbestos cleavage fragments, and evidence based on anecdotal medical reports of persons allegedly exposed to ZAI -- must be excluded under the *Daubert* standard. Even if such "evidence" were accepted, proper scientific analysis demonstrates that the airborne asbestos levels and lifetime cumulative exposures are far less than those established by government regulators as necessary to exceed a conservative or theoretical acceptable risk range.

ZAI Claimants offer no epidemiological evidence as to any causal relationship between the presence of asbestos in ZAI and disease, much less any credible scientific evidence that the presence or disturbance of ZAI would double the risk of an asbestos-related disease. They attempt to overcome this deficiency in evidence by relying upon a "no safe level" argument, that there is a risk of disease from any exposure to any amount of asbestos. This "no safe level" causation argument is not credible scientific evidence and has been rejected by the courts and by regulatory agencies that have established an acceptable risk range. Moreover, this argument flies in the face of the toxicological law of dose-response, that is, that the potential for disease is a function of the frequency, duration and magnitude of exposures to asbestos over a person's entire lifetime.

No one has ever contracted an asbestos-related disease and no one ever will contract an asbestos-related disease as a result of the presence or disturbance of ZAI in an attic. Accordingly, summary judgment on the threshold issue of whether ZAI creates an unreasonable risk of harm should be entered in favor of Grace and the claims of ZAI Claimants should be dismissed.

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